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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,568

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Ichiro Koguma

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DICKSTEIN SHAPIRO LLP

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EXAMINER

FORTUNA, ANA M

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/531,568	Applicant(s) KOGUMA ET AL.	
	Examiner Ana M. Fortuna	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 15-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 15-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/29/07, 10/28/05, 3/6/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 15-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. US 7,140,496. Although the conflicting claims are not identical, they are not patentably distinct from each other because the membrane in the patent, when operated at the conditions as in the present invention inherently produce the same permeation rate for globulin, and same virus retention; the membrane in the patent and in the present invention have the same structure, are made from the same material and conditions and have the same pore size. The membrane in the present invention is disclosed as having the same open pore ratio, and is made from the same process (compare specifications). The claims in the present invention are directed to the “membrane”, and

not to a process of using the membrane, and the separation properties are inherent or obvious based on the membrane structure.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 5-19, 22-24, 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charkoudian (US 7, 284,668). Patent '668 discloses a membrane discloses a hydrophilic microporous thermoplastic resin membrane, e.g. pdvf membrane, which is hydrophilized by graft polymerization of vinyl monomers, e.g. acrylamides, polyacrylamides, as in claims 1 and 29; the membrane is asymmetric and has a pore size within the claimed ranges (abstract, column 4, lines 45-column 5, line47; column 7, lines 9-65; column 11, lines 4-60; column 17, second paragraph). Filtering bovine immunoglobulin (IgM) and voiding membrane fouling by the IgM is further discloses (column 9, lines 31-48). Regarding claims 1, 22,-24, 28-31, the patent ('668) and the present invention both used asymmetric continuous support and treat the support with the same type of hydrophilic agents on the same thermoplastic material, for these reasons and because the pore size of the microporous membrane support are within the same range, the membrane appears to inherently have the same permeation rate for Globulin when contacted with a solution or dispersion containing the globulin under the same conditions; or these results can be predicted by the skilled artisan at the

time this invention was made. As to claims 17-19, the contact angle can also be generated by treating the same polymeric base membrane (PVDF) by grafting the same hydrophilic compounds or monomers.

4. Claims 20-21, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charkoudian (US 7,284,668) as applied to claims 1, 15-19, 22-24, 28-31 above, and further in view of Tracik et al (US 7,108,791). Patent '668 is silent about virus, porcine parvovirus membrane separation logarithmic reduction and separation rate, and or operating pressure, or the porcine parvovirus. As discussed above, the membrane flux is dependent on membrane pore size, and pressure conditions, for the same hydrophilic coating compound; patent '668 discloses the support with a range of pore sized between 0.05 to 10 microns (column 1, lines 24-33). Patent '791 teaches removing porcine parvovirus by using pvdf hydropilized membranes with a pore size of 0.5 to 10 microns with asymmetric structure (abstract, column 8, lines 36-59; column 10, lines 3-49; column 11, lines 1-50, and column 15, last paragraph- column 16, line 11), filtering IgG is further disclosed (column 30, lines 43-50). The skilled in this art at the time the invention was made based on the teaching of patent '791 can predict the virus separation or porcene parvovirus retention by the hydrophilic ultrafiltration/microfiltration membrane of '688, based on the virus size. The flux at a particular operating pressure can be predicted for a membrane having the same support and treated by the same hydrophilic modifier on skilled in this art selecting a large microporous size can be able to retain the viruses with the application of low pressure, since microfiltration is a low operating process. Tailoring the

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membrane pore size the skilled in the art can be able to control flux, e.g. permeation rate. The membrane of the invention is modified substantially by the same hydrophilic compounds and method as in patent '668, and uses the same support material and pore size; patent '791 teaches the virus size and its retention by hydrophilic membrane. The skilled artisan at the time this invention was made can select a membrane with a nanometer size lower than the virus size in order to retain the virus with the membrane (see size of the porcine virus in patent '791).

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Patent 5,788,862, 4,618,533, 6,096,213, 7,073,671 are cited as teaching hydrophilic membrane modification of hydrophobic asymmetric supports.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M. Fortuna whose telephone number is (571) 272-1141. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ana M Fortuna
Primary Examiner
Art Unit 1797

/Ana M Fortuna/
Primary Examiner, Art Unit 1797
March 10, 2008